

Appl. No. 09/461,774

REMARKS

The Office Action of September 22, 2003 presents the examination of claims 1-9. The present paper cancels claims 1-26 and adds claims 27-47.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-7 stand rejected under 35 U.S.C. § 112, second paragraph for alleged indefiniteness in the recitation of the term "substantially". Claims 1-7 have been canceled, rendering this rejection moot.

New claims 27-47 do not include the term "substantially". Accordingly, the instant rejection should not be applied to the present claims.

The amendment of the claims does not narrow them, but merely defines the terms "substantially immunoreactive" and "substantially non-immunoreactive" by using numerical values to describe the degree of immunoreactivity with any particular sample.

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Rejection under 35 U.S.C. § 102(b)

Claims 1-7 stand rejected under 35 U.S.C. § 102(b) as anticipated by Thybo. Claims 1-7 have been canceled rendering this rejection moot. Applicants submit that the rejection should not be applied to the present claims.

The Examiner takes a position that Thybo describes control study titers of 0.7 and that such a titer constitutes a "substantially nonimmunoreactive" serum, in particular in comparison with a titer of 1.15 that is deemed "substantially reactive".

Applicants submit that the language of the present claims clarifies that the antigens of the present invention exhibit an immunoreactivity profile distinct from that of the antigens described by Thybo. Accordingly, the instant rejection should not be applied to the present claims.

Furthermore, the Examiner might take note that Thybo et al. describe their antigens as having molecular weights of 17 and 28 kDa. On the other hand, the data in Figure 3 clearly show that the molecular weights of the antigens identified in the working

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examples of the specification are of different molecular weights. While the claims should not be interpreted as limited to the working examples, and the molecular weights are not recited as a limitation in the claims, Applicants nonetheless submit that the data in Figure 3 are evidence that the antigens of the invention are distinct from those described by Thybo et al.

For all of the above reasons, the instant rejection should not be applied to the present claims.

Rejection under 35 U.S.C. § 112, first paragraph

Claim 9 is rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of adequate enablement of the invention. Claim 9 is canceled, rendering this rejection moot. Applicants submit that this rejection should not be applied to the present claims.

The present claims include functional language regarding immunoreactivity with sera obtained from certain sources. Thus, the new claims are limited to those proteins or compositions that meet the functional limitations that define an operable diagnostic test. Furthermore, even though the skilled artisan may not be able to know before the fact the particular amino acid sequence of a polypeptide that is operable, the

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specification clearly describes methods for testing any desired polypeptide for operability. Example 1 describes how to make an extract from any particular *Mycobacteria* species. Example 2 describes how to separate the proteins of the sample and determine which are the relevant antigens. Example 7 describes the functional testing required to determine whether a particular antigen meets the limitations with respect to reactivity with sera from infected and non-infected patients. Cloning of DNA encoding the desired antigens is described in Examples 4 and 5 and thus the skilled artisan is provided with the means to easily make any desired embodiment of the invention. Thus, no undue experimentation is needed to determine the operable scope of the present claims and so they should be considered enabled.

The present application well-describes and claims patentable subject matter. The favorable action of allowance of the pending claims and passage of the application to issue is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell (Reg. No. 36,623) at the

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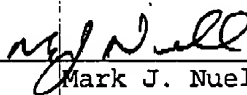
telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By



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